Before the
FEDERAL COMMUNICATIONS COMMISSION
Washington, DC 20554

In the Matter of	)	
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Biotronik, Inc.	)	
	)	
Request for Waiver of the Frequency Monitoring Requirements of the Medical Implant Communications Service Rules	)	ET Docket No. 03-92

COMMENTS OF BIOTRONIK, INC.

Biotronik, Inc. ("Biotronik"), by its attorneys, submits these comments on its pending request for waiver of the frequency monitoring requirements of the Medical Implant Communications Service ("MICS") rules to allow its cardiac implant devices to emit periodic scheduled transmissions.[1]

In its waiver request, Biotronik demonstrated to the Commission, and to the satisfaction of the National Telecommunications and Information Administration ("NTIA"), that its implant devices are designed so that they will not cause interference to, and will withstand interference from, other MICS users and primary Federal uses of the 402-405 MHz band. Biotronik further demonstrated that requiring compliance with the frequency monitoring requirements of the MICS rules would impose an undue burden on Biotronik and would not serve the needs of medical implant patients.

Accordingly, Biotronik urges the Commission to act expeditiously in granting its waiver request so that physicians can resume using periodic transmissions as a means to monitor and to intervene early in their patients' treatment and improve the quality of their lives.

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[1] *See Biotronik, Inc. Files Request for Waiver of the Frequency Monitoring Rules for Cardiac Implant Devices*, Public Notice, ET Docket No. 03-92, DA 03-1778 (rel. May 27, 2003); *see also* Biotronik, Inc.'s Request for Waiver (filed Mar. 26, 2003) ("Waiver Request").

I. BIOTRONIK HAS RESOLVED INTERFERENCE CONCERNS TO NTIA'S SATISFACTION.

In initially denying Biotronik's original waiver request,[2] the Commission stated that it would give "considerable deference" to NTIA in determining the potential impact of a MICS rule waiver on primary Federal users of the 402-405 MHz band.[3] Recently, with a better explanation from Biotronik of the function of periodic scheduled transmissions, NTIA submitted a letter to the Commission expressing support for Biotronik's revised waiver request.[4]

At the time of Biotronik's original waiver request, NTIA opposed the request due to its concern that Federal government operations in the 402-405 MHz band, in particular the use of radiosondes in the Meteorological Aids Service ("Metaids"), would disrupt periodic transmissions from Biotronik's devices and thereby endanger the health and safety of implant patients.[5] In its revised waiver request Biotronik has demonstrated that NTIA's concern is unfounded because periodic transmissions serve an important, but not life-critical, function in the treatment of cardiac patients.

The periodic scheduled transmissions emitted by Biotronik's devices are used to compile trend data on an implant patient's cardiac condition over time. This trend data is reviewed by the patient's monitoring physician and may be used for early diagnosis and treatment of a potentially life-threatening condition. Given this configuration, periodic transmissions cannot be used for the purpose of immediate response to a life-threatening situation and they are

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[2] *See* Petition for Reconsideration or Waiver of Biotronik, Inc., FCC ID PG6BA0T (filed Apr. 08, 2002).
[3] *In re Biotronik, Inc., Equipment Authorization for the Medical Implant Communications Service*, Memorandum Opinion and Order, FCC Identifier No. PG6BA0T, 18 FCC Rcd 3027, ¶ 18 (2003) ("*Philos MO&O*").
[4] *See* Letter from Frederick R. Wentland, Acting Associate Administrator, Office of Spectrum Management, NTIA, to Edmond J. Thomas, Office of Engineering and Technology, FCC (May 22, 2003) ("NTIA Letter").
[5] *See* NTIA Letter at 2.

not intended to replace traditional emergency health intervention services, such as 9-1-1.[6]

With this understanding of the non-critical function of periodic transmissions, NTIA recently submitted a letter to the Commission expressing no objection to the grant of Biotronik's waiver request and finding that the occurrence of interference to Biotronik's implants from any source would not affect the health or safety of an implant patient.[7] In its letter, NTIA states that it can now support Biotronik's waiver request, subject to certain conditions.[8] With one minor clarification,[9] Biotronik has no objection to NTIA's proposed limitations on a waiver grant, to the extent such limitations are deemed necessary.[10]

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[6] *See* Waiver Request at 7-8.

[7] *See* NTIA Letter at 2 ("An interference occurrence to the Biotronik periodic transmissions, caused by a federal radiosonde or other sources, would not affect the health or safety of an implant patient.").

[8] Specifically, NTIA states that it will support a waiver of the MICS rules for Biotronik's current line of cardiac implants and future like devices if: (1) the waiver applies to implanted devices only and not to external equipment; (2) the waiver is limited to the device characteristics discussed in Biotronik's waiver request (*i.e.*, peak power, periodic transmission duration, number of transmissions per day); (3) the waiver authorizes only non-critical communications; and (4) the waiver stipulates that potential interference to Biotronik's devices may occur on a regular basis in some areas of the U.S. where radiosondes are launched and that information should be provided to medical professionals regarding this possibility. *See* NTIA Letter at 2-3.

[9] Specifically, in its letter NTIA requests that Biotronik's waiver be "limited to the device characteristics (*i.e.*, peak power, periodic transmission duration, and transmissions per day) discussed in the [waiver request]." NTIA Letter at 2. While Biotronik's waiver request identified the operating characteristics for the Philos and Belos device lines, the waiver also is intended to cover like devices manufactured in the future. Obviously, Biotronik did not, and could not, describe the specific operating characteristics of such future devices in its waiver request. The Commission, therefore, should work with NTIA to clarify this statement.

[10] Biotronik notes that that only its implanted devices transmit in the 402-405 MHz band, and that associated external equipment does not operate in the band. Further, as already explained, Biotronik's remote-monitoring system is designed to transmit only non-critical data.

II. BIOTRONIK HAS DEMONSTRATED THAT COMPLIANCE WITH THE FREQUENCY MONITORING REQUIREMENTS OF THE MICS RULES WOULD IMPOSE AN UNDUE BURDEN ON BIOTRONIK AND WOULD NOT SERVE THE NEEDS OF PATIENTS.

In initially denying Biotronik's original waiver request,[11] the Commission found that Biotronik did not demonstrate that there is a hardship in complying with the frequency monitoring requirements, or that a compliant device could not just as effectively serve patient needs.[12] In its revised waiver request, Biotronik has satisfied the Commission's waiver standard.

Absent a waiver, Biotronik would have to re-engineer and redesign all of its implant devices to incorporate bi-directional technology in order to comply with the frequency monitoring requirements of the MICS rules. Such changes would be unnecessarily costly and time-consuming, especially given the negligible risk of interference caused by or to Biotronik's devices.[13] In addition, due to the present state of the art of medical implant devices,[14] it is unlikely that Biotronik would be able to manufacture a bi-directional device in the near future. In the interim, cardiac patients will be deprived of the proven clinical benefits that Biotronik's unidirectional remote-monitoring technology offers.

Indeed, members of the medical community have expressed vigorous support for Biotronik's waiver request and report that one-way periodic transmissions can be used effectively and reliably to diagnose serious heart conditions early.[15] The letters from medical professionals filed with the

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[11] *See* Petition for Reconsideration or Waiver of Biotronik, Inc., FCC ID PG6BA0T (filed Apr. 08, 2002).
[12] *See Philos MO&O* at ¶ 18.
[13] *See* Waiver Request at 5-7.
[14] Specifically, cardiac implant technology is limited by size and battery-life. In order to accommodate a bi-directional circuit in its devices, Biotronik would have to increase substantially the size of its implants and account for the additional power demands on the implant's battery reserve. *See* Waiver request at 8-9.
[15] *See* Letter from Niraj Varma, M.D., of University Hospitals of Cleveland (filed Apr. 1, 2003); Letter from Farrell D. Pierson, M.D., of West Knoxville Heart, P.C. (filed Apr. 2,

Commission demonstrate that physicians use periodic transmissions to monitor the condition of implant patients over time and to intervene early if a problem is detected. Support from cardiologists attest to the fact that periodic transmissions improve patient quality of life, reduce the need for frequent office visits, and, most importantly, save lives. Significantly, these physicians also report that cardiac patients currently are waiting to receive the proven benefits of Biotronik's periodic transmission technology, but cannot do so until the Commission grants its waiver request.

CONCLUSION

For the foregoing reasons, good cause exists for, and the public interest would be served by, the immediate grant of Biotronik's request for a permanent waiver of the frequency monitoring requirements of the MICS rules. Biotronik respectfully requests that the Commission act expeditiously to grant its waiver request so that cardiac implant patients may continue receiving the medical benefits of the periodic scheduled transmissions.

Respectfully submitted,

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2003); Letter from L. Gabriel Camero, M.D., of St. John Hospital and Medical Center (filed Apr. 7, 2003); Letter from Alistair Fyfe, M.D., of The Dallas Heart Group (filed Apr. 14, 2003); Letter from Joseph C. Pennington, III, M.D. of Delaware heart Group, P.A. (filed May 6, 2003); and Letter from William M. Bailey, M.D., of Lake Charles Memorial Heart and Vascular Center (filed May 6, 2003). Biotronik requests that these letters be incorporated into the docket the Commission has assigned to its waiver request.